Application No. 10/532,580

Attorney Docket No. P27726

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Jin-Hoi KIM

Examiner: Kimberly MAKAR

Appln. No. : 10/532,580

(National Stage of PCT/KR2003/002339)

I.A. Filed : November 4, 2003

Confirmation No.: 4797

For

: PORCINE UROPLAKIN II PROMOTER AND THE PRODUCTION METHOD OF USEFUL PROTEINS USING SAID PROMOTER

RESPONSE TO RESTRICTION REQUIREMENT

U.S. Patent and Trademark Office Customer Service Window, Mail Stop <u>Missing Parts</u> Randolph Building 401 Dulany Street Alexandria, VA 22314

Sir:

This paper responds to the Restriction Requirement mailed January 30, 2007, which sets a one-month period for response, to end February 28, 2007. Inasmuch as Applicants timely file this response, Applicants submit no additional fee for its consideration. However, if the Office deems any fee due for consideration of this Response, authorization is expressly given to charge such fee to Deposit Account No. 19-0089.

Restriction Requirement

In the Restriction Requirement, the Examiner alleges that four distinct species of generic inventions are contained in this application, namely:

Group I. Claim(s) 13-25, allegedly drawn to porcine uroplakin II promoters and expression vector.

Group II. Claim(s) 26-34, allegedly drawn to fertilized ovas comprising vectors comprising porcine uroplakin II promoters.

Group III. Claim(s) 35-52, allegedly drawn to transgenic animals comprising vectors further comprising porcine uroplakin II promoters.

Group IV. Claim(s) 53-61, drawn to methods of producing useful proteins utilizing porcine uroplakin II promoters.

Election

In response to the Restriction Requirement, Applicants elect Group I (claims 13-25), with traverse.

Applicants' traversal is based upon the fact that the Restriction Requirement fails to satisfy the requirements for supporting a restriction requirement under the PCT Rules. PCT Rules 13.1 and 13.2 state that an international application must relate to one invention only or, if there is more than one invention, those inventions must be so linked as to form a single general inventive concept (Rule 13.1). Inventions are considered linked so as to form a single general inventive concept only when there is a technical relationship involving one or more of the same or corresponding "special technical features." The expression "special technical features" means those technical features that define a contribution which each of the inventions, considered as a whole, makes over the prior art (Rule 13.2).

Additionally, Applicants respectfully note that Annex B to the PCT Rules states:

- (c) Independent and Dependent Claims. Unity of invention has to be considered in the first place only in relation to the independent claims in an international application and not the dependent claims. By "dependent" claim is meant a claim which contains all the features of another claim and is in the same category of claim as that other claim (the expression "category of claim" referring to the classification of claims according to the subject matter of the invention claimed for example, product, process, use or apparatus or means, etc.).
- (i) If the independent claims avoid the prior art and satisfy the requirement of unity of invention, no problem of lack of unity arises in respect of any claims that depend on the independent claims. In particular, it does not matter if a dependent claim itself contains a further invention. Equally, no problem arises in the case of a genus/species situation where the genus claim avoids the prior

art. Moreover, no problem arises in the case of a combination/subcombination situation where the subcombination claim avoids the prior art and the combination claim includes all the features of the subcombination.

In the Restriction Requirement, the Office considers Groups II-IV (claims 26-61), as lacking unity of invention. However, Applicants note that claims 26-61 are dependent claims, which the Annex to the PCT Rules specifically advises cannot be considered for unity of invention purposes. The Restriction Requirement is improper for this reason alone.

Applicants note that the Patent Office identifies that the claims all share the feature of the porcine uroplakin II promoters. The Patent Office then asserts that the porcine uroplakin II promoters are shown in the art, and then, based on that conclusion, asserts that the claims must therefore lack unity of invention. Applicants specifically reserve the right to rebut the Examiner's conclusions regarding the effect of the art on the pending claims.

Applicants also note that the Patent Office, after concluding (improperly, in Applicants' opinion), that the claims lack Unity of Invention, proceeds to divide them based upon distinctness. This is not an acceptable criterion for Restriction for an application filed under 35 U.S.C. § 371. The Restriction Requirement is improper for this reason as well.

Finally, Applicants note that the Patent Office has (improperly) restricted claims into separate Groups, despite the fact that the claims all share a common technical feature and despite the fact that the claims all ultimately depend from one independent claim. The Restriction is based solely upon the Patent Office's conclusion that the subject matter of that independent claim is found in the prior art (which, as noted above, Applicants intend to rebut). Applicants respectfully point out that upon finding that the subject matter of that independent claim is allowable over the art, the Patent Office will be required to rejoin all claims that recite the features of that "special technical feature."

In view of the foregoing remarks, Applicants respectfully submit that the Restriction Requirement is improper and should be withdrawn.

Should the Examiner have any further questions, the Examiner is invited to contact the undersigned at the below-listed telephone number.

Respectfully submitted,

Jin-Hoi KIM

Bruce H. Bernstein

Reg. No. 29,027

42,920

February 28, 2007 GREENBLUM & BERNSTEIN, P.L.C. 1950 Roland Clarke Place Reston, VA 20191 (703) 716-1191